

REMARKS

The application has been reviewed in light of the Office Action dated August 6, 2009. Claims 1, 5, 7, 9 and 11 and 12 are pending in this application, with claims 1 and 9 being in independent form. Claims 1 and 9 have been amended, claims 2, 4 and 10 have been canceled and claims 11 and 12 have been added. It is submitted that no new matter has been added and no new issues have been raised by the present Amendment.

Claims 1, 2, 4, 5, 7, 9 and 10 were rejected under 35 U.S.C. §103(a) as allegedly obvious from U.S. Patent 6,524,251 to Rabiner et al. in view of U.S. Patent 5,931,787 to Dietz et al. and U.S. Patent 5,954,637 to Francis. Applicants have carefully considered the Examiner's comments and the cited art, and respectfully submit independent claims 1 and 9 are patentable over the cited art, for at least the following reasons.

Independent claim 1 relates to a catheter for insertion into the human body and which includes one or more optionally scanning ultrasonic transducers as well as a surgical instrument to be operated from the outside. The catheter comprises at least two parts of a substantially completely circular or partially circular cross section, where a rod is inserted between said parts and at the end is provided with an ultrasonic transducer. The completely or partially circular parts are surrounded by an outer tube passed over the completely or partially circular parts, and where the surface of at least one of the completely or partially circular parts is provided with a longitudinal groove for the insertion of the surgical instrument. The completely or partially circular parts removably engage each other and are kept together by said outer tube when the catheter is assembled. The partially circular parts include abutting surfaces shaped so that they can be locked relative to one another. The completely or partially circular parts are capable of being removed from the outer tube and disengaged from each other for sterilization/disinfecting purposes. The surgical instrument is formed by a needle for the introduction of a substance or

for the extraction of tissue samples and wherein the longitudinal groove in the surface of one of the completely or partially circular parts is shaped such that the needle extends immediately below and parallel to the outer tube.

The present disclosure relates to a catheter for insertion into the human body that is very user-friendly and is easy to disassemble for disinfecting and sterilizing purposes. The catheter is formed of at least two parts of a substantially completely circular or partially circular cross section which include abutting surfaces shaped so that they can be locked relative to one another. The completely or partially circular parts are capable of being removed from the outer tube and disengaged from each other for sterilization/disinfecting purposes. Accordingly, the present catheters can be readily broken down after use so that the parts can be more easily and more completely disinfected and sterilized. The parts can also be readily reassembled. Furthermore, since the longitudinal groove is in the surface of the completely or partially circular parts and is shaped so that the needle extends immediately below and parallel to the outer tube, the needle can be inserted into the human body through the device without requiring another puncture to be made in the patient.

Rabiner et al., as understood by Applicants, relates to an ultrasonic device for tissue ablation and sheath for use therewith. Fig. 3F shows a sheath with two semi-cylindrical halves that are connected to each other by one or more connecting means. The Office Action cites Col. 9, lines 6-11 and Col. 10, lines 12-14 of Rabiner et al as allegedly disclosing the surface of at least one of the parts 109 is provided with a longitudinal groove for the insertion of a surgical instrument. Applicants respectfully disagree.

Rabiner et al. describes providing aspiration channels. For example, Rabiner et al. states:

“Such an aspiration channel is provided either inside the lumen of the sheath, or along the exterior surface of the sheath, or both. In these

embodiments, the aspiration channel can be a second hollow sheath nested within the first sheath, of the aspiration channel can be formed in the body of the sheath.” (Col. 9, lines 6-11, emphasis added)

Rabiner et al. makes no reference to these “aspiration channels” being used for insertion of surgical instruments.

Rabiner et al. does describe that the sheath can allow for the introduction of another surgical device. For example:

“In another embodiment, the sheath allows for the introduction of another surgical device, for example, flexible biopsy forceps, capable of manipulating tissues into a tissue space, such that the surgical device can hold the tissue in proximity with the probe.” (Col. 10, lines 12-17.)

However, Rabiner et al. does not indicate where this surgical device would be inserted. The other surgical device (probe 22) is inserted through the center of the sheath. Accordingly, a person of ordinary skill in the art would appear to read Rabiner et al., as disclosing that the “another surgical device” is also inserted through the center of the sheath.

Furthermore, as conceded in the Office Action, there is no indication in Rabiner et al. that the two semi-cylindrical halves are separable in any manner.

Dietz et al. was cited as allegedly teaching a longitudinal groove. As understood by Applicants, Dietz et al. relates to a sheath and methods of ultrasonic guidance for biopsy and catheter insertion. As shown in Dietz et al., a keyhole-shaped slot 60 is provided so that a needle inserted through a separate skin puncture (col. 7, lines 44-51) can be inserted into a desired body organ. As shown, slot 60 allows the needle to be inserted at an angle to the device so that it can be placed in the field of view 50 of transducer 18.

However, Applicants find no teaching or suggestion in Rabiner et al. and Dietz et al. that the longitudinal groove in the surface of one of the completely or partially circular parts is shaped such that the needle extends immediately below and parallel to the outer tube, as

claimed.

The Office Action also acknowledges that the combination of Rabiner et al. and Dietz et al. does not directly disclose the circular or partially circular cross section parts being removably engageable with one another. The Office Action cites Francis as allegedly disclosing two housing pieces removably engageable and locked relative to one another. Applicants respectfully disagree.

Francis relates to a multi-use disposable endoscope capable of being sterilized and reused for a number of surgical procedures and then discarded. The Office Action states that Francis teaches two housing pieces 110a, 110b removably engageable and locked relative to one another, citing Figure 2.

As understood by Applicants, in Francis, housing half sections 110, 110b include pins and a tongue and groove arrangement for securing the half sections together. The tongue and groove arrangement “**forms a fluid tight seal at the interface of half sections 110a, 110b, thus, precluding the passage of fluids within the housing 102 during and subsequent to sterilization**” (col. 4, lines 43 – 61.)

That is, as understood by Applicants, Francis discloses that the housing 102 is sealed to *prevent fluids* from entering the housing during sterilization. Francis **does not** allow the housing parts to be disengaged for sterilization as claimed. Applicants respectfully submit that Francis teaches away the parts capable of being removed from the outer tube and disengaged from each other for sterilization/disinfecting purposes, as recited in independent claim 1.

Accordingly, Applicants respectfully submit independent claim 1 is patentable over the cited art. Independent claim 9 is believed to be patentable over the cited art, for at least similar reasons.

Furthermore, Applicants find no teaching or suggestion in the cited art wherein the longitudinal groove extends at least long enough along the length of the completely or partially circular part so that during use, a first end of the longitudinal groove is outside the human body and a second end of the longitudinal groove is inside the human body so that the surgical instrument can be inserted from outside the human body and into the human body via the longitudinal groove, as recited in independent claims 11 and 12.

Accordingly, Applicants submit independent claims 1 and 9 are now in condition for allowance.

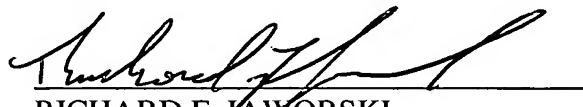
The Office is hereby authorized to charge any additional fees that may be required in connection with this amendment and to credit any overpayment to our Deposit Account No. 03-3125.

If a petition for an extension of time is required to make this response timely, this paper should be considered to be such a petition, and the Commissioner is authorized to charge the requisite fees to our Deposit Account No. 03-3125.

If a telephone interview could advance the prosecution of this application, the Examiner is respectfully requested to call the undersigned attorney.

Entry of this amendment and allowance of this application are respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard F. Jaworski', written over a horizontal line.

RICHARD F. JAWORSKI

Reg. No. 33,515

Attorney for Applicants

Cooper & Dunham LLP

Tel.: (212) 278-0400